REMARKS

The present Amendment and the following Remarks are submitted in response to the Office Communication mailed October 12, 2007. Applicant thanks the Examiner for entering the previous amendment to the claims and for indicating that the previous rejections are withdrawn.

Claim 7 is being amended. Claims 8 and 17 are being canceled. Claims 7, 10-16 and 18-19 are pending upon entry of these amendments.

No new matter is being added. The Rejections raised by the Examiner in the Communication are addressed below.

Paragraph 3. Rejection of the Claims Under 35 U.S.C. §112, First Paragraph

Claims 7-8 and 10-19 were rejected under 35 U.S.C. §112, first paragraph on the grounds that the specification does not contain an adequate written description of the claimed invention and does not reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. In particular, the Examiner alleges that Applicant was "not in possession of an antibody or an antigen-binding fragment thereof which binds specifically to a generically recited "a kinase or a subunit thereof," wherein the kinase is defined solely by its ability to phosphorylate IκBα and by approximate molecular weight." Applicant respectfully traverses this rejection.

This rejection was streamlined from a similar rejection in the previous office action. Therefore, Applicant herein incorporates by reference the arguments filed on August 13, 2007 in support of possession of the kinase of the claims. As Applicant herein amends the claims, the arguments below are adjusted and reiterated to focus on the amended claims.

In the interest of furthering prosecution and streamlining the discussion, the claims are being amended to delete "or subunit thereof." That way, any question of possession related to individual subunits, can be ignored for prosecuting the present application.

In introducing this rejection, the Examiner stated that the "kinase is defined solely by its ability to phosphorylate IκBα at the specified residues and by approximate molecular weight" (emphasis added). By making this statement, it appears that the Examiner considers structural and functional characteristics to be the only way to show possession of an invention. While structural and functional characteristics can show possession, and those characteristics disclosed in the specification will be reiterated and summarized below, another way to show possession is by actual reduction to practice (see, e.g. MPEP §2163). The criterion for this means for showing possession is stated at page 178 of Sept 2007 Rev. 6 MPEP: "showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose."

The specification shows actual reduction to practice of a representative number of species of the claimed invention. Figures 2A and 14A-B show actual isolation of at least two species of the kinase against which the claimed antibodies would be raised. As these figures are representations of both the purification and functional assays, both the structure as represented by approximate molecular weight by gel filtration chromatography (mostly eluted from the column prior to (and thus mostly larger than) the 670 kDa marker) and function, phosphorylation of IκBα are demonstrated. Other portions of Figure 2 show that the phosphorylation is at Serines 32 and 36 of IκBα. Another way the approximate molecular weight of the kinase was demonstrated was by comparison to the 20S marker on a native gel. Applicant demonstrated the presence of the kinase in more than one cell type (Figures 11). Applicant demonstrated species of the kinase which are active without stimulation, with ubiquitin stimulation, with TNFα stimulation, with MEKK1 stimulation. Regardless of the species, the phosphorylation of IκBα was demonstrated. These studies and others detailed in the specification demonstrate that Applicant constructed the kinase against which the claimed antibodies would be raised and determined that the kinase would work for its intended purpose.

Another means by which an Applicant is allowed to show possession, as expressed by the Examiner, is by disclosure of sufficient identifying characteristics that one of skill in the art would recognize possession. "Kinase" is an art-recognized term, so when one of skill in the art sees that the material isolated by Applicant phosphorylates IκBα, that practitioner would recognize that the material is a kinase. Phosphorylation of IκBα at serine residues 32 and 36 is an art-recognized way to identify a kinase by its substrate specificity. This concept has been accepted by the field, as evidenced by the Scheidereit publication provided by the Examiner (see Table 1, page 6687). This is a unique feature of the kinase disclosed in the specification and is a way to distinguish this kinase from the kinases in the prior art (discussed in the specification, e.g., at page 21, line 23 to page 22, line 6, Fig. 15A and page 43, lines 4-8). Another art-recognized characteristic of biological macromolecules is their approximate molecular weight. Examples of how well recognized molecular weights for distinguishing macromolecules can be found in common names of some macromolecules, such as "p53," "p105," "hsp90," "gp120," which all refer to macromolecules primarily by their approximate molecular weights, but whose identities are readily understood by those of skill in the art. One of skill in the art also would recognize the correlation between the calibration markers of the gel filtration column, elution mostly prior to the 670 kDa marker, and the designation of the disclosed multisubunit kinase as "approximately 700 kDa," which has evolved into "700-900 kDa kinase complex, as evidenced by the Scheidereit publication. These terms serve to limit the claims in a manner sufficient for one of skill in the art to recognize that, at the time the application was filed, Applicant was in possession of the kinase of the recited substrate specificity and the recited size and thus in possession of the claimed antibodies.

There are many additional ways wherein the description and actual reduction to practice disclosed in the specification describes identifying features of the kinase and thus demonstrates that Applicant had possession of the kinase and thus the claimed antibodies. For example, the specification discloses methods to isolate the complex and that the complex comprises a number of subunits, which are identified by molecular weights, p85, p70, p62, p55, p50, p43, p40, p38, p36, p33, and p31 (see, e.g., page 14, lines 4-11). This disclosure further indicates that the p85 subunit is effecting the observed phosphorylation of IκBα for further correlation of structure with the function of the complex. In addition, the specification discloses some sequences (peptide and nucleic acid) of contributors to the complex Figs. 21, 22). The specification discloses ways to activate and inhibit the kinase. Furthermore, Applicant determines the Km of the kinase (Example 19, page 107) and demonstrates an inhibition profile using inhibitors of the kinase activity (Example 24, page 112 and Fig. 24). The specification discloses cellular pathways in which the kinase operates and demonstrates consequences of the activity of the kinase. All these aspects of the disclosure provide measurable and reproducible identifying characteristics of the kinase and demonstrate to one of skill in the art, that at the time of filing, Applicant was in possession of the kinase and thus the claimed antibodies.

In summary, Applicant has provided a kinase identifiable by a unique function and approximate molecular weight, with correlation of structure with function and has reduced to practice a representative number of species in the claimed genus. Applicant provided this disclosure concurrent with actual reduction to practice using methods well-known to those of skill in the art. The Examiner has not provided evidence that Applicant's assertions are untrue, on the contrary, evidence provided by the Examiner evidence the verity of Applicant's disclosure. One of skill in the art readily would recognize possession of antibodies which specifically recognize this complex. In view of these remarks, the Applicant respectfully requests withdrawal of this rejection.

Paragraph 5. Rejection of the Claims Under 35 U.S.C. §102

Claims 7-8, 10-19 were rejected under 35 U.S.C. §§102(a) and 102(e) as allegedly being anticipated by McGuire et al., as evidenced by Scheidereit. The basis of this rejection is the disclosure of antibodies to hsp90 in McGuire et al. and the later discovery that hsp90 is a component of the kinase against which the claimed antibodies are raised. In response, Applicant herein amends the claims to delete "or a subunit thereof." Therefore, while some antibodies raised against the complex may recognize hsp90, not all antibodies will do so. Conversely, due to the association of hsp90 with the complex, and thus likely masking some of the hsp90 epitopes, not all antibodies to hsp90 will bind the complex. In view of this amendment and these remarks, withdrawal of the rejection is respectfully requested.

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CONCLUSION

The foregoing amendments and remarks are being made to place the Application in condition for allowance. Applicant respectfully requests the timely allowance of the pending claims because, in view of these amendments and remarks, Applicant respectfully submits that the objections to the specification and claims and the rejections of the claims under 35 U.S.C. §§ 112 and 102 are overcome. Applicant believes that this application is now in condition for allowance. Early notice to this effect is solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned. If the Examiner disapproves of Applicant's amendments and remarks in this response, Applicant requests a prompt mailing of a notice to that effect.

This paper is being filed timely as a request for a three month extension of time is filed concurrently herewith. No additional extensions of time are required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

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